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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,686	06/18/2001	Sandrine Segura	016800-445	9187
7590 10/19/2005			EXAMINER	
Norman H. Stepno, Esquire BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,686

Applicant(s)

SEGURA ET AL

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8-10,12-18,20-29,31-43,47-50,93 and 94 is/are pending in the application.
- 4a) Of the above claim(s) 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8-10,12-18,20-29,31-43,47,48,50,93 and 94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2005 has been entered.

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 8-10, 12-18, 20-29, 31-43, 47-48, 50, 93-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,106,848 in view of Bowser et al.. '848 claims an oil in water emulsion comprising at least a glycol, at least one emulsifying agent comprising anionic amphiphilic polymer, and at least one biological active agents, wherein the anionic amphiphilic polymer is a copolymer of acrylic acid and (major) and fatty ester of acrylic acid (minor). The biological active agents in '848 claims are essentially identical to those herein claimed, including antidandruff agents. '848 do not particularly claims that the biological active agents are solid

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micronized particles. Bowser et al. teaches that reduced particle size of insoluble bioactive agent would lead to a better efficacy. See, particularly, columns 2-3. Therefore, it would have been obvious to use micronized particles of those active agents that not soluble because micronized particles, such as those disclosed by Bowser et al, would have been expected to lead better efficacy. The optimization of a result effective parameter, e.g., particle size, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further, incorporation of other well-known cosmetic agents into a cosmetic composition would have been within the skill of artisan.

Claim Rejections 35 U.S. C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 8-10, 15-18, 20-29, 40-43, 47-48, 50, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. (EP 0 268 164) in view of the Handbook of Cosmetic Science and Technology, and in further view of Bowser et al.

The instant invention is directed toward an oil-in-water emulsion comprising a discontinuous fatty phase dispersed in a continuous aqueous phase that comprises a biologically active agent and an effective amount of an emulsifying system, wherein the active agent is non-

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solubilized. in the emulsion and 80% has a diameter of 1-10 μm and 50% has a diameter of less than 5 μm , wherein the active can be selected from the Markush group recited in the instant independent claim, and methods of treating acne.

Lochhead et al. teach oil-in-water emulsions which contain a modified polymer which is a copolymer of an acrylic acid and a smaller amount of a long chain acrylate monomer, wherein the modified polymers function as primary emulsifiers or surfactants. The modified polymer is made by polymerizing a preponderant amount of carboxylic monomer and a lesser amount of a long chain acrylate ester, i.e. 50-99% of carboxylic monomer and 1-50% acrylate ester. Acrylic acid is taught as the preferred carboxylic monomer and higher alkyl acrylic esters, such as decyl acrylate are taught as acrylate monomers. The oil phase comprises 0.1-60% of the emulsion, the modified polymer comprises 0.05-3% of the emulsion, and the aqueous phase comprises 40-99.9% of the emulsion. The emulsion has a pH of about less than 6 is disclosed. A mixture of silicone oil and mineral oil is taught as comprising the oil phase. Conventional oil-in-water emulsions preferably have a particle size of less than 10 microns and preferably 0.1-5 microns. The emulsion has an average size of 50 microns and a range of 10-100 microns. Cyclomethicone is taught as an additive in the oil phase. Sorbitol is taught as a humectant that can be added to the emulsion in an amount of 1-10% of the emulsion. Methyl paraben, propyl paraben, and imidazolidenyl urea are taught as preservatives in the emulsion, wherein these compounds are also antibacterial agents that are insoluble in the aqueous phase of the emulsion, and comprise 0.05-0.5% of the composition. The emulsion is taught as a cleansing cream or lotion that flushes the skin and pore openings, wherein flushing skin and pore openings treats acne. See pg. 2, line 28-pg. 14, line 10. Lochhead et al. further teaches that other well-known agents may be

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incorporated into the emulsion, such as co-emulsifiers, bodying agents, emollients, humectants, preservatives. See, particularly, page4, lines 35-46.

The reference lacks the express teaching of the percent amount of the particles as the form of biological active agents.

The Handbook of Cosmetic Science and Technology teaches that a smaller emulsion particle size will lead to a greater interfacial area and, hence, a higher propensity to form a structure, and further teaches that the rate of phase separation can be reduced by reducing the dispersed phase particle size. See pages 115 and 117. Bowser et al. further teaches that particle size for insoluble biological active agent is a result effective parameter. In the particular situation, for zinc pyrithione, an antidandruff agent, particle size smaller than 5 um are preferred. See, particularly, columns 2-3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the oil-in-water emulsion of Lochhead et al. as having a diameter of 10 microns because of the expectation of achieving greater interfacial area and a propensity to form a structure and decreased phase separation, as taught by the Handbook of Cosmetic Science and Technology. Furthermore, a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955), and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Further, it would have been obvious to use the oil in water emulsion as a base formulation with any biological active agents, such as the biocide zinc pyrithione, for skin cleansing, protection. Further, the optimization of a result effective parameter, e.g., particle size, is considered within

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the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. finally, incorporation of other well-known cosmetic agents into a cosmetic composition would have been within the skill of artisan.

For the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 211 1.03.

Claims 12, 37-39. rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology as applied to claims 1, 2, 4, 8-10, 15-18, 20-29, 40-43, 47-48, 50 above, and further in view of Pisson et al. (5,882,633).

Lochhead et al. is applied as discussed above. The reference lacks a surfactant emulsifier and a thickener.

Pisson et al. teach cosmetic and/or dermatological compositions. Exemplified is an oil-in-water emulsion comprising Arlacel 165 (glyceryl and PEG-100, surfactant emulsifier) and acrylic acid/C10-C30 alkyl acrylate, wherein Arlacel 165 is a co-emulsifier for the copolymer. Guar gums and celluloses are taught as thickener additives. See Col. 10, line 3-Col. 13, line 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add Arlacel 165, as taught by Pisson et al., to the composition of Lochhead et al.

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because of the expectation of achieving an oil-in-water emulsion with less phase separation, greater solubility between the two phases, and greater stability.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the thickeners taught by Pisson et al. to the emulsions of Lochhead et al. because of the expectation of achieving a product with a thickener consistency that is easily applied as a film over the skin.

While the amount of gelling agent is not explicitly taught, it is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Additionally, in Col. 10 of Pisson et al., the reference teaches that one of ordinary skill in the art would know how much of an additive to add to the emulsion to impart the advantageous property of the additive without adversely affecting the purpose of the emulsion.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology and in view of Pisson et al. as applied to claims 1, 2, 4, 8-10, 15-18, 20-29, 40-43, 47-48, 50 above, and further in view of Kaplan et al (5,916,543).

Lochhead et al. and Pisson et al. are applied as discussed above. The reference lacks a co-surfactant.

Kaplan teaches oil-in-water emulsions. Cetareth-20 (co-surfactant, fatty alkyl ether) is taught as a known oil-in-water emulsifier that enhances emulsion stability and that can be combined with other emulsifiers for enhancing emulsion stability. See Col. 2, line 15-Col. 3,

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line 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate ceteareth-20, as taught by Kaplan, into the composition of Lochhead et al. because of the expectation of achieving an emulsion with enhanced stability.

Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lochhead et al. in view of the Handbook of Cosmetic Science and Technology as applied to claims 1, 2, 4, 8-10, 15-18, 20-29, 40-43, 47-48, 50 above, and further in view of Kim et al. (5,980,939).

Lochhead et al. is applied as discussed above. The reference lacks wetting agents.

Kim et al. teach poloxamer 124 as a solubilizer for medicinal components and lipid emulsions and as thermally stable and a gelling agent. Poloxamer 124 is exemplified as comprising approximately 4% of the composition. See Col. 6, line 27-Col. 7, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add poloxamer 124, as taught by Kim et al., to the composition of Lochhead et al. because of the expectation of achieving an emulsion that is thermally stable and in which the active agents are well solubilized.

Claims 1, 2, 4, 8-10, 12-18, 20-29, 31-43, 47-48, 50, 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preuilh et al. (EP 0 832 647, US 6,106,848 is an equivalent) in view of the Handbook of Cosmetic Science and Technology, and in further view of Bowser et al.

Preuilh et al. teach an oil in water emulsion comprising at least a glycol, at least one emulsifying agent comprising an anionic amphiphilic polymer, and at least one biological active agents, wherein the anionic amphiphilic polymer is a copolymer of acrylic acid and (major) and

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fatty ester of acrylic acid (minor) See, particularly, the claims. The preferred copolymers are the same as herein preferred. See, particularly, column 2, lines 10-64. The biological active agents disclosed by Preuilh are essentially identical to those herein claimed, including antidandruff agents. See, particularly, the claims. The composition comprising 0.1 to 6% of the emulsifying agent (the copolymer), 0.0001-20% of active agents, 5-50% of oil phase, 10-70% of aqueous phase. The composition may also comprising co-emulsifier, thickener, and other well-known cosmetic agents. See, particularly, columns 3-6.

Preuilh et al. do not particularly claims that the biological active agents are solid micronized particles.

Bowser et al. teaches that reduced particle size of insoluble bioactive agent would lead to a better efficacy. See, particularly, columns 2-3. Therefore, it would have been obvious to use micronized particles of those active agents that not soluble because micronized particles, such as those disclosed by Bowser et al, would have been expected to lead better efficacy. The optimization of a result effective parameter, e.g., particle size, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. Further, incorporation of other well-known cosmetic agents into a cosmetic composition would have been within the skill of artisan.

Response to the Arguments

Applicants' amendments and remarks submitted July 28, 2005 have been fully considered, but are moot in view of the new ground rejections set forth above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1617